K070476

MAR 26 2007

Attachment V

510(k) Summary

1.General Information

Submitter:	AllMed Systems Inc. 9232 Klemetson Drive Pleasanton CA 94588
Phone:	925-468-0433
Fax	925-399-5984
Contact Person	Peter Allen
Date Prepared	15th February 2007

2. Names

Device Name	Revolix 120 Laser System
Common Name	2.01micron Laser System
Classification Name	Laser Surgical Instrument and accessories

3. Predicate Device

Lumenis/Coherent Medical – VersaPulse Ho:YAG 100 watt
Trimedyne Omnipulse Max 80 watt
RevoLix 90 watt

4. Product Description

The RevoLix 120 laser system is diode pump solid state surgical laser system operating at a wavelength of 2.01 micron. The purpose of the laser is the ablation, coagulation, dissection and resection of soft tissue. The laser is designed for open surgery, laparoscopic and surgical applications in aqueous media. The laser power is delivered via standard silica laser fibers. The distal tip is guided by a handpiece or endoscopic/laparoscopic surgical instrument.

It consists of:

Laser Console with Internal Computer
Control Panel and Display
A fiber optic delivery system
Footswitch

5. Indications for Use

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Urethral Strictures
Bladder Neck Incisions (BNI)
Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors.
Ablation of Benign Prostatic Hypertrophy (BHP),
Transurethral incision of the prostate (TUIP)
Laser Resection of the Prostrate (HoLRP)
Laser Enuculeation of the Prostate (HoLEP)
Laser Ablation of the Prostate (HoLAP)
Condylomas
Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Appendectomy
Polyps
Biopsy
Gall Bladder calculi
Biliary/Bile duct calculi
Ulcers
Gastric ulcers
Duodenal ulcers
Non Bleeding Ulcers
Pancreatitas
Hemorrhoids
Cholecystectomy
Benign and Malignant Neoplasm
Angiodysplasia
Colorectal cancer
Telangiectasias
Telangiectasias of the Osler-Weber-Renu disease

Vascular Malformation
Gastritis
Esophagitis
Esophageal ulcers
Varices
Colitis
Mallory-Weiss tear
Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

Laryngeal Lesions
Airway obstructions including carcinoma
Polyps and Granulomas
Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)

Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation
Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

Endonasal/sinus Surgery
Partial turbinectomy
Polypectomy
Dacryocystorhinostomy
Frontal Sinusotomy
Ethmoidectomy
Maxillary antrostomy
Functional endoscopic sinus surgery
Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
Tonsillectomy
Adenoidectomy

Dermatology and Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

Basal Cell Carcinomas
Lesions of skin and subcutaneous tissue
Skin tags
Plantar warts

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Cholecystectomy
Lysis of adhesion
Appendectomy
Biopsy
Skin incision
Tissue dissection
Excision of external tumors and lesions
Complete or partial resection of internal organs, tumors and lesions
Mastectomy
Hepatectomy
Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy
Pilonidal Cystectomy
Resection of lipoma
Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Statis Ulcer
Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including
Percutaneous Laser Disc Decompression/Discectomy
Foraminoplasty
Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery.

6. Rationale for Substantial Equivalence

The Revolix 120 laser system with fiber optic delivery devices share the same intended use, indications for use, similar design features and functional features and therefore are substantially equivalent to the Lumenis VersaPulse Laser

7. Conclusion

The Revolix 120 Laser System with fiber optic delivery devices were found to be substantially equivalent to similar currently marketed and predicate surgical laser systems and delivery devices.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070476

K070476 pdf

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AllMed Systems Inc.
% Mr. Peter Allen
President
9232 Klemetson Drive
Pleasanton, California 94588

MAR 26 2007

Re: K070476
Trade/Device Name: RevoLix 120 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 13, 2007
Received: March 14, 2007

Dear Mr. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

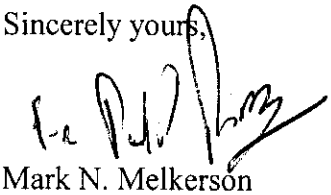
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: RevoLix 120 Laser System

Indications For Use:

The Revolix 120 laser systems and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery.and Arthroscopy

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostrate (HoLRP)
- Laser Enuculeation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number:

Device Name: RevoLix 120 Laser System

Indications For Use:

Ulcers
Gastric ulcers
Duodenal ulcers
Non Bleeding Ulcers
Pancreatitas
Hemorrhoids
Cholecystectomy
Benign and Malignant Neoplasm
Angiodysplasia
Colorectal cancer
Telangiectasias
Telangiectasias of the Osler-Weber-Renu disease
Vascular Malformation
Gastritis
Esophagitis
Esophageal ulcers
Varices
Colitis
Mallory-Weiss tear
Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

Laryngeal Lesions
Airway obstructions including carcinoma
Polyps and Granulomas
Palliation of obstructing carcinomas of the tracheobronchial tree

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number:

Device Name: RevoLix 120 Laser System

Indications For Use:

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)

Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation
Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

Endonasal/sinus Surgery
Partial turbinectomy
Polypectomy
Dacryocystorhinostomy
Frontal Sinusotomy
Ethmoidectomy
Maxillary antrostomy
Functional endoscopic sinus surgery
Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
Tonsillectomy
Adenoidectomy

Dermatology and Plastic Surgery

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number:

Device Name: RevoLix 120 Laser System

Indications For Use:

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

Basal Cell Carcinomas
Lesions of skin and subcutaneous tissue
Skin tags
Plantar warts

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Cholecystectomy
Lysis of adhesion
Appendectomy
Biopsy
Skin incision
Tissue dissection
Excision of external tumors and lesions
Complete or partial resection of internal organs, tumors and lesions
Mastectomy
Hepatectomy
Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number:

Device Name: RevoLix 120 Laser System

Indications For Use:

Pilonidal Cystectomy
Resection of lipoma
Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Statis Ulcer
Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including
Percutaneous Laser Disc Decompression/Discectomy
Foraminoplasty
Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)